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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,677	03/24/2000	SVEND BIRKELUND	BIRKELUND=1	2720

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EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/446,677

Applicant(s)

BIRKELUND ET AL.

Examiner

Khatol S Shahnan-Shah

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 15-18, 22-25 and 27-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 6, 8, 9, 11, 13 and 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 7, 10, 22-25 and 27-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

1. Applicants' amendment and response received March 26, 2004 is acknowledged. Claims 1, 5, 6, 9, 13, 15, 22-25 and 27-33 have been amended. Claims 12, 14, 19-21, 26 and 34-44 have been canceled. Specification pages 3, 6, 7, 8, 14, 15, 22, 28, 30 and 32 have been amended.
2. Currently claims 1-11, 13, 15-18, 22-25 and 27-33 are pending.
3. Claims 5, 7, 10, 22-25 and 27-33 are under consideration. Claims 1-4, 6, 8, 9, 11, 13 and 15-18 are withdrawn from consideration as being drawn to non-elected inventions.
4. The declaration under 37 CFR 1.132 by Svend Birkelund filed 3/26/04 is acknowledged. The declaration is insufficient to overcome the rejection of claims 5,7 and 10 under 102 (b) as being anticipated by Melgosa as set forth in the last Office action because: see paragraphs 15, 16 and 17 below.

Prior Citations of Title 35 Sections

5. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Objections Withdrawn

6. Objection to specification in regard to sequence identifiers, made in paragraph 9 of the office action mailed January 23, 2004 is withdrawn in view of applicants' amendments.
7. Objection to specification, made in paragraph 10 of the office action mailed January 23, 2004 is withdrawn in view of applicants' amendments.
8. Objection to claims 27, 28, 29 and 30 made in paragraph 11 of the office action mailed January 23, 2004 is withdrawn in view of applicants' amendments.

Objections Moot

9. Objection to claims 34, 37, 38 and 44 made in paragraph 11 of the office action mailed January 23, 2004 is moot in view of applicants' cancellation of said claims.

Rejections Moot

10. Rejection of claims 26, 43 and 44 made in paragraph 13 of the office action mailed January 23, 2004 is moot in view of applicants' cancellation of said claims.

11. Rejection of claims 19-21, 26 and 34- 44 made in paragraph 14 of the office action mailed January 23, 2004 is moot in view of applicants' cancellation of said claims.

Rejections Withdrawn

12. Rejection of claims 5, 7 and 10 under 35 USC § First Paragraph, made in paragraph 12 of the office action mailed January 23, 2004 is withdrawn in view of applicants' amendments.

Rejections Maintained

13. Rejection of claims 31 and 32 under 35 U.S.C. 112, second paragraph, made in paragraph 12 of the office action mailed January 23, 2004 is maintained. The applicants have not amended the claims. Claims 31 and 32 are still indefinite because they refer to the figures.

See MPEP 2173.05(s) Reference to Figures or Tables

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993).

Art Unit: 1645

14. Rejection of claims 5, 7, 10, 22-25 and 27-33 under 35 U.S.C. 112, first paragraph, in regard to **new matter** made in paragraph 14 of the office action mailed January 23, 2004 is maintained.

Applicants' arguments filed March 23, 2004 have been fully considered and are not persuasive.

Applicants argue that they do not use the exact language, however, they have pointed to pages 3, 8, 11 and 18-20 of the specification for the descriptive support for "said protein being free of any other chlamydial protein". Applicants further argue these following points:

A. We expressly contemplate vaccine use (see, e.g., P3, L33; P18, L21-24; P19, L10-P20, L18), which implies that the protein must be purified sufficiently to be pharmaceutically acceptable.

B. We teach recombinant expression of the protein (P8, L21-22); P11, L24-26; P20, L19-28). If the host cells are not infected with Chlamydia, they will inherently be free of chlamydial proteins other than that encoded by the deliberately cloned gene.

C. We disclose kits comprising none or more" of the proteins of SEQ ID NO: 2-24. The none" implies that in some embodiments, the kit provides only one of the twelve recited proteins, implying exclusion of the other 11.

The examiner has carefully evaluated those pages and lines applicants have pointed to.

None of these pages explicitly or implicitly recite the limitation "said protein being free of any other chlamydial protein". For example page 3 line 33 recite "the development of vaccine against infection with this microorganism" or page 8, line 21-22 recite "The full length omp4 was cloned into an expression vector system that allowed the expression of the omp4 polypeptide". None of these lines recite the limitation "said protein being free of any other chlamydial protein" nor merely imply said limitation. Therefore the new limitation in the claims is still considered new matter. *In re Rasussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step or a compound from a disclosure. See MPEP 608.04.

15. The rejection of claim 5 under 35 USC § 102(b), made in paragraph 14 of the office action mailed June 03, 2002 is maintained.

The rejection was as stated below:

Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Melgosa et al. (FEMS Microbiology Letters Vol. 112, No. 2, pp. 199-204, September 1993). Prior art already made of record.

Claim 5 is drawn to a protein derived from *Chlamydia pneumoniae* having the amino acid sequence shown in SEQ ID NO: 2 or a variant or subsequence thereof having a sequence similarity of at least 50% and similar biological function.

Melgosa et al. teach a protein derived from *Chlamydia pneumoniae*. Melgosa et al. teach a 98-kDa protein from outer membrane complex of *Chlamydia pneumoniae* (see abstract and page 202). SEQ ID NO: 2 or a variant of the claimed invention will be inherent in the 98-kDa protein taught by Melgosa et al.

Applicants' arguments filed March 23, 2004 have been fully considered and are not persuasive.

Applicants argue the claim recites an isolated protein and it is evident that Melgosa et al. in fact failed to isolate any of the recited chlamydial proteins. Applicants further argue that while Melogosa thought he had a single 98 kDa protein he was mistaken.

It is the examiner's position that Melgosa et al. do teach isolated proteins. Melgosa isolated the proteins by extracting of outermembrane proteins from elementary bodies (EBs) and than the purified proteins were separated by electrophoresis (SDS-page) see page 300.

Art Unit: 1645

The declaration by Svend Birkelund filed 3/26/04 does not overcome this rejection.

16. The rejection of claim 7 under 35 USC § 102(b), made in paragraph 15 of the office action mailed June 03, 2002 (paper number 22) is maintained.

The rejection was as stated below:

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by Melgosa et al. (FEMS Microbiology Letters Vol. 112, No. 2, pp. 199-204, September 1993).

Claim 7 is drawn to a kit for diagnosis of infection of a mammal with *Chlamydia pneumoniae* comprising a protein with the amino acid sequence shown in SEQ ID NO: 2 or a variant or subsequence thereof. (The examiner views the claimed kit as a product or a composition comprising a protein of *Chlamydia pneumoniae*).

Melgosa et al. teach a product or a composition for diagnosis of infection of a mammal with *Chlamydia pneumoniae* comprising a protein derived from *Chlamydia pneumoniae*. Melgosa et al. teach a composition of 98-kDa protein from outer membrane complex of *Chlamydia pneumoniae* (see abstract) This composition was used for diagnosis of *Chlamydia pneumoniae* in rabbits (see page 201). SEQ ID NO: 2 or a variant of the claimed invention will be inherent in the 98-kDa-protein composition taught by Melgosa et al.

Applicants' arguments filed March 23, 2004 have been fully considered and are not persuasive.

Applicants argue the claim recites an isolated protein and it is evident that Melgosa et al. in fact failed to isolate any of the recited chlamydial proteins. Applicants further argue that while Melogosa thought he had a single 98 kDa protein he was mistaken.

Art Unit: 1645

It is the examiner's position that Melgosa et al. do teach isolated proteins. Melgosa isolated the proteins by extracting of outer membrane proteins from elementary bodies (EBs) and then the purified proteins were separated by electrophoresis (SDS-page) see page 300. The declaration by Svend Birkelund filed 3/26/04 does not overcome this rejection.

17. The rejection of claim 10 under 35 USC § 102(b), made in paragraph 16 of the office action mailed June 03, 2002 (paper number 22) is maintained.

The rejection was as stated below:

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Melgosa et al. (FEMS Microbiology Letters Vol. 112, No. 2, pp. 199-204, September 1993).

Claim 10 is drawn to a composition for immunizing a mammal against *Chlamydia pneumoniae* comprising a protein with the amino acid sequence shown in SEQ ID NO: 2 or a variant or subsequence thereof.

Melgosa et al. teach a composition for immunizing a mammal against *Chlamydia pneumoniae* comprising a protein derived from *Chlamydia pneumoniae*. Melgosa et al. teach a composition of 98-kDa protein from outer membrane complex of *Chlamydia pneumoniae* (see abstract) This composition was used to immunize rabbits (see page 200). SEQ ID NO: 2 or a variant of the claimed invention will be inherent in the 98-kDa-protein composition taught by Melgosa et al.

Applicants' arguments filed March 23, 2004 have been fully considered and are not persuasive.

Applicants argue the claim recites an isolated protein and it is evident that Melgosa et al. in

fact failed to isolate any of the recited chlamydial proteins. Applicants further argue that while Melgosa thought he had a single 98 kDa protein he was mistaken.

It is the examiner's position that Melgosa et al. do teach isolated proteins. Melgosa isolated the proteins by extracting of outer membrane proteins from elementary bodies (EBs) and then the purified proteins were separated by electrophoresis (SDS-page) see page 300. The declaration by Svend Birkelund filed 3/26/04 does not overcome this rejection.

Conclusion

18. No claims are allowed.

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

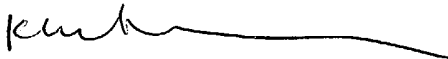
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

Art Unit: 1645

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645, July 17, 2004



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER